

April 4, 2003

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Via Electronic Transmission
Original Signed Letter via FedEx

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Comments on Proposed Rules Concerning Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002
(FDA Docket No. 02N-0278)

Dear Sir or Madam:

American Airlines respectfully submits the following comments on the Notice of Proposed Rulemaking by the Food and Drug Administration (FDA) in the *Federal Register* of February 3, 2003, concerning Prior Notice for Importation of Food under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act).¹

American strongly supports FDA's mission to protect the nation's food supply. We look forward to working with FDA to achieve the goals of the Bioterrorism Act while preserving and protecting the flow of cargo into the United States. The commercial aviation industry in this country plays a crucial role in the effective distribution of food both in the United States and around the world. Consequently, FDA should consider the scope and impact of its prior notice procedures on this country's scheduled air carriers, including American, when adopting regulations to implement the requirements of the Bioterrorism Act.

For purposes of these regulations, FDA uses the word "food" as that term is defined in the Federal Food, Drug and Cosmetic Act (FFDCA). The FFDCA defines the term "food" to mean "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article." 9 U.S.C. § 321(f). Examples of "food" identified in the proposed rules include fruits, vegetables, fish, dairy products, eggs, animal feed, food additives, dietary supplements, infant formula, beverages (including alcoholic beverages and bottled water), bakery goods, candy, and canned foods. This very broad definition of "food" would appear to include many products that may not be labeled or designated by shippers as "food" using the common sense meaning of that word. American encourages FDA to revise its definition of "food" in these regulations, so that the definition may more closely match the common sense meaning of the word "food." At a minimum, American urges FDA provide clear notification to shippers as to the scope of the term "food" in articulating the shippers' responsibilities under these regulations.

Pursuant to Section 1.276 of the proposed rules, food shipments imported into the United States solely for export to another country would nonetheless be subject to the prior notice requirement before their entry into the United States. In most cases, these "transit shipments" do not remain in the country longer than 24 hours, and during this brief time period, they are under the strict control of the airline. It is highly unlikely that any of these shipments would be inadvertently distributed inside the United States. Accordingly, it would not appear that prior notices for the importation of these transit shipments would materially benefit

¹ American also incorporates by reference the comments presented to FDA on these regulations by the Air Transport Association of America, Inc. (ATA), of which American is a member.

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FDA or enhance homeland security. However, requiring prior notice for the importation of transit shipments would present a tremendous burden for American and other cargo operators, by driving procedural and process changes that would be very costly for carriers to implement. For these reasons, we urge FDA to exclude transit shipments from the scope of the new regulations.

The proposed rules appropriately assign the duty of providing prior notice of imported food to the shipper or its agent in the United States, and not to the carrier. If the shipper fails to provide the required notice, the proposed regulations state that the food shipment may be refused admission into the United States, and subsequently removed to a secure facility (e.g., a bonded warehouse). According to the rules, removal of food shipments denied entry is to be arranged by the shipper or the carrier, but the costs of removal and storage are to be borne by the "owner, purchaser or consignee." As a practical matter, it may fall to the carrier in the first instance to find an appropriate storage facility and to facilitate the transfer of the shipment to that facility. To maintain the foregoing allocation of duties with respect to these shipments, the regulations should be revised to provide explicitly that the carrier can collect any removal, storage or disposition costs it may incur from the owner, purchaser or consignee of the shipment. The regulations also should outline the process by which the carrier may recover those costs. The regulations should address what happens if a shipment denied entry into the United States is never claimed by the owner, purchaser, or consignee.

Finally, the proposed regulations exempt "Food that is carried by an individual entering the United States in that individual's personal baggage for that individual's personal use." However, food shipped by an individual outside of the U.S. to an individual in the U.S. for personal use is not exempt. Although the individual sending the package would be required to notify the FDA, it is unclear whether the carrier accepting such a shipment for transport has any obligation to verify whether the package contains food items and if so, whether the requisite notice has been submitted. We recommend that FDA extend the exemption to food that is shipped by an individual, without monetary compensation, to an individual in the United States for personal consumption.

Thank you for the opportunity to present these comments.

Very truly yours,

A handwritten signature in black ink, reading "Kendra Harmer". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Kendra Harmer
Manager—Policies and Procedures
American Airlines Cargo Services